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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,301	01/25/2002	Mark Chasin	207.1300US	3895

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EXAMINER	
KIM, JENNIFER M	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 06/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/057,301	CHASIN ET AL.	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-93* is/are pending in the application.

4a) Of the above claim(s) *69-80,82-86,88 and 90-93* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-68,81,87 and 89* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/24/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The response filed March 21, 2005 have been received and entered into the application.

Action Summary

The rejection of record of claims 1-68, 81, 87 and 89 under judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-38 of U.S. Patent No. 6,248,345 is maintained for the reasons stated in the previous Office Action.

The objection of the specification under 35 U.S.C 112, first paragraph, is hereby expressly withdrawn in view of Applicant's response.

The rejection of claims 33-68 and 81 under 35 U.S.C. 112, first paragraph is hereby expressly withdrawn in view of Applicant's response.

The rejection of claims 10-11, 15-18, 20-21, 24, 26-31, 45,46, 48 and 49 under 35 U.S.C. 112, first paragraph is hereby expressly withdrawn in view of Applicant's response.

The rejection of claims 33-68 and 81 under 35 U.S.C. 112, second paragraph, is hereby expressly withdrawn in view of Applicant's response.

The rejection of claims 50-54 under 35 U.S.C. 112, second paragraph, is hereby expressly withdrawn in view of Applicant's response.

The rejection of claims 1-32, 87 and 89 under 35 U.S.C. 112, second paragraph, is hereby expressly withdrawn in view of Applicant's response.

The rejection of claims 33-68 under 35 U.S.C. 102 (a) as being anticipated by Berde et al (340), or (187) is being maintained for the reasons stated in the previous Office Action.

The rejection of claims 1-68, 81, 87 and 89 under 35 U.S.C. 102 (e) as being anticipated by Goldenheim et al. (345) or (335) is being maintained for the reasons stated in the previous Office Action.

The rejection of claims 1-68, 81, 87 and 89 under 35 U.S.C. 103 (a) as being obvious over Goldenheim et al. (345) or (335) is being maintained for the reasons stated in the previous Office Action.

The rejection of claims 1-68, 81, 87 and 89 under 35 U.S.C. 103 (a) as being unpatentable over Berde et al (340), or (187) is being maintained for the reasons stated in the previous Office Action.

Response to Arguments

Applicants arguments filed March 21, 2005 have been fully considered but they are not persuasive. Applicants argue with respect to the **Obvious-Type Double patenting rejection**, that the independent claims 1, 33, 35 and 81 and 89 are all directed to provision of local analgesia, local anesthesia or nerve blockade in a human

but the only in-vivo data reported in the Goldenheim '335 and '345 patents is for animals, and neither the '335 nor '345 Goldenheim patents provide Cmax or Tmax data for administration of the disclosed formulations to a human being and cannot be assumed that the formulations of either the '335 or the '345 patents could achieve in a human, the Cmax, Tmax, onset of local analgesia, local anesthesia, nerve blockade, level of local anesthetic at the site of administration, or the duration of action recited in the rejected claims. This is not persuasive because Goldenheim et al. teach the administration of same composition uses for both human and veterinary practices, as they are immediately apparent to one skilled in the art. Applicants' attention is drawn to column 3, lines 50-55, column 4, lines 1-2, column 9, lines 19-20, column 17, lines 34-35, column 20, lines 39-41, column 24, lines 37-40, and column 26, lines 12-15 and claims 1-38, wherein it teaches the administration of the composition in human. Therefore, the obviousness type double patenting rejection is deemed proper as the patent teaches the same method step of administration of the same composition comprising same active agents, same dosage amount, to a same subject (human) as set forth by Applicants' claim 1, therefore any result achievement of the Cmax, Tmax, onset of local analgesia, local anesthesia, nerve blockade, level of local anesthetic at the site of administration, or the duration of action recited would be encompassing effect of administration of the same composition to same subject taught by the cited reference.

With regard to the **rejection under 35 U.S.C. 102(a)**, Applicants argue that neither the '187 nor '340 Berde patents provide Cmax or Tmax data for administration of the disclosed formulations to a human being, it cannot be assumed that the formulation

of either the '187 or the '340 patents could achieve in a human, the Cmax, Tmax, onset of local analgesia, local anesthesia, nerve blockade, level of local anesthetic at the site of administration, or the duration of action set forth in independent claims 33 and 35. This is not persuasive because Berde patent teaches the same method step of administration of same composition comprising same active agents, same dosage amount, to a same subject (human) as set forth by Applicants' claim 1. Applicants' attention is drawn to abstract, column 7, line 60-column 8, line 4, claims 24-34, teaches the term "patient" as utilized in the Berde patent broadly refers to any animal that is to be treated with the composition including humans. Therefore any result achievement of the Cmax, Tmax, onset of local analgesia, local anesthesia, nerve blockade, level of local anesthetic at the site of administration, or the duration of action recited would be an inherent effect of administration of the same composition to same subject taught by the cited reference.

With regard to the **rejection under 35 U.S.C. 102(e)**, Applicants argue that neither the '335 nor '345 Goldenheim patents provide Cmax or Tmax data for administration of the disclosed formulation to a human, it cannot be assumed that the formulations of either the '335 or the '345 patents could achieve in a human, the Cmax, Tmax, onset of local analgesia, local anesthesia, nerve blockade, level of local anesthetic at the site of administration, or the duration of action recited in the rejected claims. This is not persuasive because, as explained above, Goldenheim et al. teach the administration of same composition uses or both human and veterinary practice as they are immediately apparent to one skilled in the art.

Applicants' attention is drawn to column 3, lines 50-55, column 4, lines 1-2, column 9, lines 19-20, column 17, lines 34-35, column 20, lines 39-41, column 24, lines 37-40, and column 26, lines 12-15 and claims 1-38, wherein it teaches the administration of the composition in human. Therefore, the obviousness type double patenting rejection is deemed proper as the patent teaches same method step of administration of same composition comprising active agents, same dosage amount, to a same subject (human) as set forth by Applicants' claim 1, therefore any result achievement of the Cmax, Tmax, onset of local analgesia, local anesthesia, nerve blockade, level of local anesthetic at the site of administration, or the duration of action recited would be encompassed by administration of the same composition to same subject taught by the cited reference.

With regard to the **rejection under 35 U.S.C. 103(a)**, Applicants argue that none of the references provide Cmax or Tmax data for administration of the disclosed formulations to a human being, it cannot be assumed that the formulations of the prior art (Goldenheim '335, '345 or the Berde et al. '187, '340) could achieve in a human, the Cmax, Tmax, onset of local analgesia, local anesthesia, nerve blockade, level of local anesthetic at the site of administration, or the duration of action recited in the rejected claims. This is not persuasive because the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir.

1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it is clear that the cited references teaches the claimed bupivacaine and dexamethasone as old and well known in combination with various pharmaceutical carriers and excipients in a lactic acid, glycolic acid polymer microsphere dosage form. It is well known that this medicament is taught as useful for treating pain, viewed by the skilled artisan as indistinguishable form that use herein envisioned. Further, route of administration, e.g., intramuscular etc; mode of administration, flavors, surfactant are all deemed obvious since they are all within the knowledge of the skilled pharmacologist and represent conventional formulations and modes of administration. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

In view of the above, the Office Action of April 4, 2004 is deemed proper and asserted with full force and repeated herein to obviate applicants' claims.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sreenivasan Padmanabhan
Supervisory Examiner
Art Unit 1617

Jmk
June 20, 2005